UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION *This document relates to:* *Track Three Cases*	MDL 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

PLAINTIFFS' TRIAL BRIEF

At trial, Plaintiffs will proceed solely on the claim for common-law absolute public nuisance. Plaintiffs present the Court with their "roadmap" for the trial:

PLAINTIFFS' CLAIM: ABSOLUTE PUBLIC NUISANCE

The issues of fact for trial are: (1) whether a public nuisance exists; (2) whether the opioid epidemic interferes with public health and public safety rights; (3) whether Defendants' conduct proximately caused the public nuisance; and (4) whether Defendants' conduct was intentional or unlawful.

WHETHER A PUBLIC NUISANCE EXISTS; AND WHETHER THE OPIOID EPIDEMIC INTERFERES WITH PUBLIC HEALTH AND PUBLIC SAFETY RIGHTS

On their nuisance claim, Plaintiffs will show that a public nuisance exists and that the opioid epidemic in Lake and Trumbull Counties constitutes an unreasonable interference with public health, public safety, public peace, or public comfort, and, in particular, that the interference is unreasonable because it is significant, or is of a continuing nature or has produced a permanent or long-lasting effect upon the public right, or that the underlying conduct giving rise to it is contrary to law. *See Cincinnati v. Beretta U.S.A. Corp.*, 2002-Ohio-2480, ¶ 8, 95 Ohio St. 3d 416, 419 (Ohio 2002); Restatement (Second) of Torts § 821B (1979).

CAUSATION

Plaintiffs will show that each of the Defendants' wrongful conduct was a "substantial factor" in bringing about or maintaining the nuisance and was not a remote cause. *See Pang v. Minch*, 53 Ohio St.3d 186, 559 N.E.2d 1313, 1324 (1990) (where plaintiff suffers a single injury as a result of the tortious acts of multiple defendants, the burden of proof is on the plaintiff to demonstrate that the conduct of each defendant was a substantial factor in producing the harm; thereafter, the burden of persuasion shifts to the defendants to demonstrate that the harm produced by their separate tortious acts is capable of apportionment); Restatement (Second) of Torts § 431, comment b (1965) ("where the evidence permits a reasonable finding that the defendant's conduct had some effect" the question becomes "whether the effect was substantial rather than negligible"); *Halloran v. Barnard*, 2017-Ohio-1069, ¶ 5.

Plaintiffs will prove that the dispensing and distribution level failures resulted in excessive quantities of opioid pills pouring into the counties beginning in the early 2000's, from orders and prescriptions that should never have been filled which increased the risk of diversion and misuse. This resulted in opioid deaths, opioid overdoses, and opioid use disorders that materially affected the health and safety of these communities. Plaintiffs will also show that diversion and improper use of these drugs was the foreseeable, indeed the expected, consequence of Defendants' conduct and the reason for the legal obligations imposed on them with respect to the distribution and dispensing of controlled substances.

Plaintiffs will further show that the excessive pills, and the resulting diversion and misuse, foreseeably led to increases in the use of illegally-manufactured or distributed opioids, including heroin and so-called "Chinese" fentanyl, and that the harms associated with this increase contributed to the public nuisance and were a foreseeable consequence of Defendants' conduct.

DEFENDANTS' CONDUCT AS DISPENSERS AND DISTRIBUTORS

Plaintiffs will show that the Defendants, as registrants under the Federal Controlled Substances Act, failed to comply with their obligations as both dispensers and distributers of opioid prescription products. Plaintiffs will demonstrate that the Defendants' conduct was intentional or unlawful, or both, and that each Defendant's misconduct increased the risk of diversion and substantially contributed to the creation of a public nuisance in both counties.

The Federal Controlled Substances Act, 21 U.S.C. § 801 et seq, was enacted by Congress in 1970 out of a recognition that the illegal manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American People. This preamble recognized that although many controlled substances have a useful and legitimate medical purpose, these drugs can be dangerous because they are addictive and often diverted to illicit use, misuse, or abuse.

As registrants, the Defendants were required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. § 1301.71 (a). Plaintiffs will demonstrate that as dispensers and distributors of controlled substances, Defendants failed to design and implement systems that provided those controls beginning in the early 2000's and continuing thereafter. This misconduct significantly contributed to an oversupply of opioid prescription pills that increased the risk of diversion and caused the public nuisance in these two counties.

As ***dispensers*** of controlled substances, the CSA imposed legal duties on Defendants.

The Defendants' pharmacists are required to review prescriptions presented to them to determine if the prescription is appropriate and safe for the patient (reviewing factors such as the reason for the issuance of the prescription, potential adverse effects, potential drug-drug

interactions, and abuse, misuse, or noncompliance with drug therapy). This process is commonly referred to as Drug Utilization Review (DUR). As part of their assessment, pharmacists must consider whether the "prescription" presented is in fact valid and issued by a licensed professional in the usual course of professional practice. This common-sense requirement is codified into laws and regulations including the CSA and state laws. *See* OAC 4729-5-21(A).

Chain pharmacies have important responsibilities and duties in the practice of pharmacy and are subject to certain legal obligations under the CSA. "The corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself." *See Holiday CVS, LLC, d/b/a/ CVS Pharmacy Nos. 219 and 5195*, Decision and Order, Fed Reg. Vol. 77, No. 198, p. 62316-62346, at 62341 (October 12, 2012).

Duty to Collect and Maintain Prescription Data. Defendants were required to maintain systems and methods to collect, store, and retain prescription dispensing data and records. *See* 21 C.F.R. § 1304.22(c). This record-keeping requirement is intended as a guard against diversion. *See Med. Shoppe-Jonesborough v. Drug Enf't Admin.*, 300 F. App'x 409, 411 (6th Cir. 2008) ("Medicine Shoppe fell short of meeting its duty to maintain accurate records of the controlled substances it dispensed.").

Documentation related to the dispensing of controlled substances is a critical component of any system or program. Documentation identifies critical factors, such as red flags, whether the pharmacist resolved the red flag(s), and information alerting to the occurrence or possibility of diversion.

Plaintiffs will provide evidence and testimony about the kinds of data Defendants were required to collect—and in many cases did collect—which could have been used to help identify red flags and guard against diversion.

Duty to Identify Red Flags. In addition to merely collecting the data, the CSA imposed a duty on Defendants to actually do something with the data in order to fulfill its fundamental obligation to guard against diversion. Specifically, to comply with 21 C.F.R. § 1306.04(a), Defendants were required to maintain systems, policies, or procedures to identify red flags.

Plaintiffs will demonstrate that many red flags are impossible for individual pharmacists to identify on their own—such as pattern prescribing (e.g., the same drugs, in the same quantities, coming from the same doctor)—and that Defendants could have, if they chose to, maintained systems to aggregate and analyze their prescription data to identify such red flags. Indeed, Defendants were in the best position to do so. Plaintiffs will further show that computer algorithms could have easily been utilized to identify patterns of problematic prescribing, but that Defendants chose not to implement such systems, and instead chose to remain willfully blind to the data it had at its fingertips.

Moreover, the Ohio Automated Rx Reporting System (OARRS) is a statewide electronic database which contains dispensing information on scheduled controlled substances. Pharmacies must submit prescription information into OARRS when a controlled substance is dispensed. In 2011, Ohio started requiring pharmacists to review OARRS prior to dispensing prescription opioids if the pharmacist became "aware" of certain red flags. *See* OAC 4729-5-20, Eff. 10/27/2011.[1]

In 2015, with the opioid epidemic growing out of control, Ohio's DUR requirements were further updated to mandate that "at a minimum, a pharmacist shall request and review an OARRS report covering at least a one-year time period, including a border state's information when the pharmacist is practicing in a county bordering another state" when:

- a patient starts a new drug;

[1] Text of the 2011 version of OAC 4729-5-20 is conveniently available on the Internet Archive at https://web.archive.org/web/20121108031703/http://codes.ohio.gov/oac/4729-5-20 (last visited August 19, 2021).

- an OARRS report has not been reviewed for the patient within the year;
- a prescriber is located outside the local area;
- a patient is located outside the local area;
- a pharmacist has reason to believe the patient has received a prescription from more than one prescriber in the preceding 3 months; or
- the patient is exhibiting signs of potential abuse.

See OAC 4729-5-20.

Plaintiffs will show Defendants failed to integrate their systems with OARRS, failed to require and adequately train and enforce procedures to check OARRS, and failed to train their pharmacists in general on identifying and resolving red flags.

Duty to Resolve Red Flags. In addition to collecting prescription data and developing systems to identify red flags, Defendants had a duty to provide information about red flags to their pharmacists. A pharmacy cannot collect prescription data and identify red flags and then not provide that information to its pharmacists—leaving their "pharmacist-employees with the sole responsibility to ensure only proper prescriptions are filled." *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2020 WL 5642173, at *3 (N.D. Ohio Sept. 22, 2020). Rather, a corporate chain pharmacy must provide its pharmacy stores and employees access to databases, information, training and tools (utilizing whatever infrastructure necessary such as intranet and internet systems) to assist in determining the validity of a prescription such as whether a prescriber is appropriately licensed and other due diligence related to the filling and validity of a controlled substance prescription.

Plaintiffs will prove Defendants failed to comply with these legal obligations and that they "engaged in *intentional* conduct to dispense opioids in a manner that caused an oversupply of highly addictive drugs." *See In re Nat'l Prescription Opiate Litig.*, 477 F. Supp. 3d 613, 633 (N.D. Ohio 2020) (holding the requisite intent for an absolute nuisance is showing the defendant "intended to

bring about the conditions which are in fact found to be a nuisance") (citations omitted). Despite being keenly aware of the oversupply of opioids, Defendants not only kept their pharmacists blind to the red-flag-revealing data they had in their possession, but Defendants also required and rewarded speed and volume of opioid dispensing, while minimizing standards of safety, care, and due diligence by its pharmacists. Defendants also deliberately implemented performance metrics and prescription quotas to increase the dispensing of opioids.

Such conduct was both unlawful and intentional, and Plaintiffs will show how such conduct resulted in a massive oversupply and diversion of prescription opioids, which created a public nuisance in Lake and Trumbull Counties.

As ***distributers*** of controlled substances, the CSA imposed legal duties on Defendants:

Duty to Identify Suspicious Orders. Defendants, as distributers, had a duty under 21 C.F.R. § 1301.74(b) to design and operate a system to identify suspicious orders of opioids. Plaintiffs will prove Defendants chose not to implement effective SOM systems as required by the CSA.

Duty to Report Suspicious Orders. Once Defendants identified suspicious orders of opioids, it had a duty to report such suspicious orders to the DEA. *See* 21 C.F.R. § 1301.74(b). Plaintiffs will prove Defendants chose not to report suspicious orders to the DEA as required by the CSA.

Duty to Not Ship Suspicious Orders. The CSA statutory and regulatory duties to maintain effective controls against diversion include a duty to not ship suspicious orders until the red flags are resolved. Plaintiffs will prove that Defendants chose to ship suspicious orders without conducting due diligence and resolving the red flags as required by the CSA.

Such conduct was both intentional and unlawful, and Plaintiffs will show how such conduct resulted in a massive oversupply and diversion of prescription opioids, which created a public nuisance in Lake and Trumbell Counties.

ENFORCEMENT ACTIONS AGAINST DEFENDANTS

Plaintiffs will prove Defendants were aware that their failures to guard against diversion were illegal under the CSA. Defendants have faced extensive enforcement actions by the DEA.

CVS

- March 28, 2013, CVS paid a fine of $11,000,000.00 (resolving claims that CVS violated the CSA by, *inter alia*, filling prescriptions for certain prescribers whose DEA registration numbers were not current or valid. *See* CVS-MDLT1-000060822 – 00006082.
- September 2, 2014, CVS paid a $1,912,500 fine for filling prescriptions at eight different pharmacies, written by Dr. Pedro Garcia during a time period during which his Texas Department of Public Safety Controlled Substances registration was expired. *See* CVS-MDLT1-00060907 – 000060914.
- May 12, 2015, CVS paid a fine of $22,000,000.00. The Settlement resolved claims that CVS failed "to fulfill its corresponding responsibility to ensure that CVS dispensed controlled substances only pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R. §1306.64." *See* CVS-MDLT1-000060796 – 000060804.
- July 24, 2015, CVS paid a $50,000 fine for failing to keep accurate records. *See* CVS-MDLT1-000099702 –000099704.
- August 7, 2015, CVS paid a $450,000 fine for wrongfully filling prescriptions. *See* CVS-MDLT1-000060847 – 000060855.
- December 18, 2015, CVS paid a fine of $345,000.00. Inspection demonstrated that CVS again failed its CSA obligations. *See* CVS-MDLT1-00060915-00060921.
- December 31, 2015, the DEA issued a letter of admonishment for violations in distributing HCPs at the CVS Indiana distribution center. *See* CVS-MDLT1-00008014 – 00008015; CVS-MDLT1- 000076135.
- February 12, 2016, CVS paid a fine of $8,000,000.00. CVS acknowledged that between 2008 and 2012, "certain CVS/pharmacy retail stores in Maryland did dispense certain controlled substances in a manner not fully consistent with their compliance obligations under the CSA." *See* CVS-MDLT1-000060805-00060811.
- June 30, 2016, CVS agreed to pay $3.5 Million to resolve allegations that 50 of its stores violated the Controlled Substances Act by filling forged prescriptions for controlled substances – mostly addictive painkillers – more than 500 times between 2011 and 2014.
- October 20, 2016, CVS paid a $600,000 fine for failing to store prescriptions properly. *See* CVS-MDLT1 000060830 – 000060838.
- July 5, 2017, CVS paid a fine of $5,000,000.00. The Settlement resolved claims for, *inter alia*, failing to provide effective controls and procedures to guard against theft and diversion of controlled substances pursuant to 21 C.F.R. §1301.71(a). *See* CVS-MDLT1 000060856-000060871.

- June 15, 2018, CVS agreed to pay a $1,500,000.00 fine. The Settlement resolved claims that between February, 2013 and January, 2015, CVS failed to report to the DEA in writing, within one business day of discovery, thefts or significant losses of controlled substances. *See* CVS-MDLT1-000060839 – 000060846.
- July 29, 2018, CVS agreed to pay a $1,000,000 fine. The Settlement resolved claims that CVS violated the CSA and failed to keep proper records. *See* CVS-MDLT1-000060812 – 000060821.

RITE AID

- January 9, 2009, Rite Aid agreed to pay $5 million in civil penalties to resolve allegations that Rite Aid knowingly filled prescriptions for controlled substances that were not issued for legitimate medical purposes.
- March 9, 2017, Rite Aid paid $834,200 to the United States to settle claims that Rite Aid pharmacies in Los Angeles, California dispensed and/or recorded controlled substances using a medical practitioner's incorrect or invalid DEA registration number.
- December 31, 2018, the DEA and the Rhode Island Attorney General announced $300,000 settlement with Rite Aid for filling prescriptions of Schedule III controlled substances in excess of statutory maximums.

WALGREENS

- May 2006, the DEA sent Walgreens a Letter of Admonition citing Walgreens for record keeping inadequacies and security deficiencies at its Perrysburg Distribution Center. Specifically, the DEA found that the "formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient." *See* WAGMDL00709510.
- April 7, 2011, Walgreens entered into a Settlement Agreement with the DEA regarding allegations of non-compliance with the Controlled Substance Act wherein Walgreens had agreed to "maintain a compliance program to detect and prevent diversion of controlled substances." *See* Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387975.
- July 17, 2013, Walgreens agreed to pay $80 Million in civil penalties related to allegations that Walgreens was filling numerous prescriptions that Walgreens employees knew, or should have known, were not issued for a legitimate medical purpose.
- January 18, 2017, Walgreens agreed to pay $200,000 following an investigation by the Massachusetts Attorney General's Office, which found that Walgreens failed to track the opioid use of high-risk patients in the state's Medicaid program.

WALMART

- February 15 2007, Walmart agreed to pay a $120,000 fine. The settlement involved allegations that Walmart filled prescriptions for controlled substances under an incorrect DEA number, failed to include all required information on prescriptions, and filled prescriptions in the absence of a legitimate medical purpose. *See* WMT_MDL_000043479.

- January 6, 2009, Walmart agreed to pay a $637,000 fine and represented that it is taking good faith measures to detect and prevent diversion. *See* WMT_MDL_00004384.
- March 11, 2011, Walmart and the DOJ/DEA entered into an Administrative Memorandum of Agreement wherein Walmart agreed to maintain a proper compliance program. *See* US_DEA_0006101.
- August 31, 2015, Walmart agreed to pay a $376,000 fine. The settlement involved allegations that certain Walmart and Sam's Club pharmacies filled prescriptions issued by individual practitioners who lacked a valid DEA registration number. *See* WMT_MDL_000043507.
- December 22, 2020, the Department of Justice commenced a civil enforcement action in the U.S. District Court for the District of Delaware alleging that Walmart violated the CSA in multiple ways as the operator of its pharmacies and wholesale drug distribution centers including by unlawfully dispensing controlled substances from pharmacies it operated across the country and unlawfully distributing controlled substances to those pharmacies throughout the height of the prescription opioid crisis.

DEFENDANTS' OTHER WRONGFUL CONDUCT

Plaintiffs will also present evidence on Defendants' other conduct to demonstrate their intent, motive, and/or knowledge. Plaintiffs will show that Defendants knowingly worked in concert with opioid manufacturers to ensure that false messaging surrounding the treatment of pain and the true addictive nature of opioids was consistent and geared to increase profits for all stakeholders; that they worked together to ensure that the opioid quotas allowed by the DEA remained artificially high; and that they falsely assured the public that Defendants were working to curb the opioid epidemic.

CONCLUSION

Plaintiffs will prove their claim for absolute public nuisance and demonstrate that each Defendant engaged in intentional or unlawful conduct, or both, which substantially contributed to the creation of a public nuisance in Lake and Trumbull Counties.

Respectfully submitted,

Jayne Conroy
Simmons Hanly Conroy
112 Madison Avenue, 7th Floor
New York, NY 10016
(212) 784-6400
(212) 213-5949 (fax)
jconroy@simmonsfirm.com

Joseph F. Rice
Motley Rice LLC
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464
(843) 216-9000
(843) 216-9290 (fax)
jrice@motleyrice.com

Paul T. Farrell, Jr., Esq.
Farrell & Fuller LLC
1311 Ponce de Léon Ave., Suite 202
San Juan, PR 00907
(304) 654-8281
paul@farrellfuller.com

Plaintiffs' Co-Lead Counsel

/s/Peter H. Weinberger
Peter H. Weinberger (0022076)
Spangenberg Shibley &Liber
1001 Lakeside Ave East, Suite 1700
Cleveland, OH 44114
(216) 696-3232
(216) 696-3924 (fax)
pweinberger@spanglaw.com

Plaintiffs' Liaison Counsel

W. Mark Lanier
The Lanier Law Firm
10940 Sam Houston Pkwy N., Suite 100
Houston, TX 77064
(713) 659-5200
(713) 659-2204 (fax)
Mark.Lanier@LanierLawFirm.com

Plaintiffs' Trial Counsel

Frank L. Gallucci
Plevin & Gallucci Co., L.P.A.
55 Public Square, Suite 222
Cleveland, OH 44113
(216) 861-0804
(216) 861-5322 (fax)
FGallucci@pglawyer.com

Hunter J. Shkolnik
Napoli Shkolnik
270 Munoz Rivera Ave, Suite 201
Hato Rey, Puerto Rico 00918
(787) 493-5088, Ext. 2007
hunter@napolilaw.com

Salvatore C. Badala
Napoli Shkolnik PLLC
360 Lexington Ave., 11th Floor
New York, NY 10017
(212) 397-1000
(646) 843-7603 Fax
Sbadala@napolilaw.com

Counsel for Plaintiffs Lake County and Trumbull County, Ohio

CERTIFICATE OF SERVICE

I hereby certify that on August 19, 2021, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF system.

/s/Peter H. Weinberger
Peter H. Weinberger